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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/362,731	07/29/1999	JEAN-MARIE SAINT-REMY	01699/P.UCB.	7229

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EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/02/2002 17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/362,731	SAINT-REMY ET AL.	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/20/01* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-16 and 18-29* is/are pending in the application.

4a) Of the above claim(s) *15 & 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 15-16, 18-29 are pending.

2. Claims 15-16 stand withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions.

3. The drawings, filed 7/29/99, stand not approved. Please see PTO 948 mailed 4/20/01. Appropriate correction is required.

4. In view of the amendment filed 9/20/01, only the following rejections remain.

5. Claims 18-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated compound consisting of SEQ ID NO: 1-5 wherein said compound consisting of one allergen antigenic determinant from *Der pII* or *Der pI* which is recognized by B cell (a B cell epitope) linked by two glycine residues to at least one T cell epitope from tetanus toxoid or Influenza which triggers T cell activation for immunizing mice against house dust mite (See page 22 line 25), does not reasonably provide enablement for (1) *any* isolated compound for preventing or treating any allergy, said compound consisting of one *any* allergenic determinant which is recognized by a B cell or *any* antibody secreted by a B cell of a non-atopic individual to *any* allergen and (b) at least one antigenic determinant of *any* antigen different from said allergen which triggers T cell activation, (2) *any* compound wherein said any allergenic determinant is not recognized by a T cell, (3) *any* compound consisting of *any* allergenic determinant from major antigen of Aspergillus fumigatus, staphylococcal B enterotoxin (SEB) and bovine β-lactoglobulin, or any antibody secreted by a B cell of a non-atopic individual to any allergen such as the ones recited in claim 20, (3) *any* antigenic determinant of any antigen which triggers T cells activation is any T cell epitope of tetanus toxoid, diphtheria, mycobacterium, influenza or measles virus antigen, (4) *any* compound wherein the allergenic antigenic determinant and the antigenic determinant of the antigen are *any* peptidic sequences, (5) *any* compound wherein peptidic sequences as recited in claim 23 are bound together by a peptidic linker, (6) *any* compound wherein the peptidic linker comprises at least two of *any* amino acids, (7) *any* pharmaceutical composition comprising any compound and pharmaceutical acceptable carrier, (8)

any cosmetical composition comprising *any* compound and a cosmetical acceptable carrier, (9) *any* beverage, food or feed composition comprising any compound and a liquid, food or feed acceptable carrier, (10) *any* compound which is used as a medicament and (11) *any* compound comprises one of the following amino acid sequences selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5 for preventing or treating any allergy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons set forth in Paper No 12.

Applicants' arguments filed 9/20/01 have been fully considered but are not found persuasive.

Applicants' position is that teachings of the specification clearly enable one skilled in the art to practice the invention without undue experimentation.

The specification discloses only (1) a peptide consisting of SEQ ID NO: 2 which is a B cell epitope from Der pII (See page 23), (2) a peptide consisting of SEQ ID NO: 1 mixed with an adjuvant myramyl-dipeptide for immunization (page 25), (3) a peptide consisting of SEQ ID NO: 3 which contains a duplicate T cell epitope derived from tetanus toxoid linked to six repetitive B cell epitopes from Der pII (See page 25, example 2), (4) a peptide consisting of SEQ ID NO: 4 which contains B cell epitopes from Der pI and T cell epitopes from tetanus toxoid (See page 29), (6) a peptide consisting of SEQ ID NO: 5 which contains B cell epitopes from Der pII and T cell epitope from tetanus toxoid (page 29) for immunizing mice against house mite allergen (page 30-32) and (7) a prophetic teachings on the administration of said peptides using a humanized animal model SCID mice and a formulation for a cosmetic composition for skin hygiene on page 32, example 9.

The specification fails to teach how to make and use *any* compound comprising *any* B cell epitope from *any* allergen antigenic determinant mentioned above such as the major antigen from Aspergillus fumigatus, Staphylococcal B enterotoxin and bovine β-lactoglobulin and *any* antigenic determinant T cell epitope for preventing or treating *any* allergies. There is insufficient guidance and working examples on *any* antibody secreted by a B cell to *any* allergen of a non-atopic individual linked to *any* antigenic determinant, *any* pharmaceutical, food, beverage, feed composition for treating or preventing *any* allergy. Since there is no disclosure on demonstrating the ability of the test mice to withstand challenge from exposure to any allergen after treating any compound mentioned above, it follows that any isolated compound for preventing or treating

allergy, including dust mite, is not enabled. Given the indefinite number of undisclosed compound, it is unpredictable as to which undisclosed compound would be useful for prevent and treat all allergies.

For these reasons, the specification as filed fails to enable one skill in the art to practice the invention without undue amount of experimentation. As such, further research would be required to practice the claimed invention.

6. Claims 18-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention for the same reasons set forth in Paper No 12.

Given the absence of additional rebuttal to the outstanding rejection of record in applicant's amendment, filed 9/20/01, the rejection is maintained for the reasons set forth in Paper No 12 and reiterates below.

The specification discloses only (1) a peptide consisting of SEQ ID NO: 2 which is a B cell epitope from Der pII (See page 23), (2) a peptide consisting of SEQ ID NO: 1 mixed with an adjuvant myramyl-dipeptide for immunization (page 25), (3) a peptide consisting of SEQ ID NO: 3 which contains a duplicate T cell epitope derived from tetanus toxoid linked to six repetitive B cell epitopes from Der pII (See page 25, example 2), (4) a peptide consisting of SEQ ID NO: 4 which contains B cell epitopes from Der pI and T cell epitopes from tetanus toxoid (See page 29), (6) a peptide consisting of SEQ ID NO: 5 which contains B cell epitopes from Der pII and T cell epitope from tetanus toxoid (page 29) for immunizing mice against house mite allergen (page 30-32) and (7) a prophetic teachings on the administration of said peptides using a humanized animal model SCID mice and a formulation for a cosmetic composition for skin hygiene on page 32, example 9.

The specification does not reasonably provide a **written description** of (1) *any* isolated compound for preventing or treating any allergy, said compound consisting of one *any* allergenic determinant which is recognized by a B cell or *any* antibody secreted by a B cell of a non-atopic individual to *any* allergen and (b) at least one antigenic determinant of *any* antigen different from said allergen which triggers T cell activation, (2) *any* compound wherein said any allergenic determinant is not recognized by a T cell, (3) *any* compound consisting of *any* allergenic determinant from major antigen of Aspergillus fumigatus, staphylococcal B enterotoxin (SEB)

and bovine β-lactoglobulin, or any antibody secreted by a B cell of a non-atopic individual to any allergen such as the ones recited in claim 20, (3) *any* antigenic determinant of any antigen which triggers T cells activation is any T cell epitope of tetanus toxoid, diphtheria, mycobacterium, influenza or measles virus antigen, (4) *any* compound wherein the allergenic antigenic determinant and the antigenic determinant of the antigen are *any* peptidic sequences, (5) *any* compound wherein peptidic sequences as recited in claim 23 are bound together by a peptidic linker, (6) *any* compound wherein the peptidic linker comprises at least two of *any* amino acids, (7) *any* pharmaceutical composition comprising any compound and pharmaceutical acceptable carrier, (8) *any* cosmetical composition comprising *any* compound and a cosmetical acceptable carrier, (9) *any* beverage, food or feed composition comprising any compound and a liquid, food or feed acceptable carrier, (10) *any* compound which is used as a medicament and (11) *any* compound comprises one of the following amino acid sequences selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5 for preventing or treating any allergy.

With the exception of specific compound consisting of SEQ ID NOS: 1-5, there is no description about the structure associated with function of *any* isolated compound mentioned above. Given the lack of a written description as encompassed by the claims, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.* Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. Claims 18-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Bixler *et al.* (US Patent No 5,785,973, see entire document) for the same reasons set forth in Paper No 12.

Applicants' arguments filed 9/20/01 have been fully considered but are not found persuasive.

Applicants' position is that Bixler et al do not teach or suggest a compound of (a) at least one allergen antigenic determinant which is recognized by a B cell **or** an antibody secreted by a B cell of a non-atopic individual to said allergen and (b) at least one antigenic determinant of an antigen different from said allergen which triggers T cell activation.

However, Bixler *et al* teach a compound which is a conjugate comprising T cell epitope from diphtheria or tetanus toxin which is an antigenic determinant **unrelated to B cell determinant** (See column 8, lines 5-8, column 8, lines 21-26) conjugated to an antigenic determinant of interest (See column 8, lines 21-30, in particular) such as **B cell antigenic determinants** of ragweed, mite protein Der pI and Der pII (See column 12, lines 51-60, in particular) for enhance the production of antibodies against common allergen which is particularly useful in the immunization of infant humans whose immune system is not fully developed (See column 8, lines 44-50, in particular). The reference antigenic determinant of T cell epitope from tetanus toxoid, or diphtheria triggers T cell activation and thereof provides T cell help to B cell to increase antibodies production (See column 3, lines 36-52, in particular). The reference compound wherein the allergenic determinant and the antigen determinant of the antigen (T cell epitope) are synthesized by solid phase peptide synthesis which linked the said allergenic determinant and antigenic determinant together via peptide bonds to form a peptidic sequence (See column 16, Procedure for solid phase peptide synthesis, in particular). The reference compound can also be made by linking the allergenic determinant and antigenic determinant via a peptide linker such as lysine or cysteine residues (See column 14, lines 9-24, in particular). Bixler *et al* also teach a pharmaceutical composition comprising the reference compound and a pharmaceutical acceptable carrier (See column 15, Formulation and administration of vaccine, in particular).

Claim 19 is included in this rejection because the reference B cell antigenic determinant is obviously not recognizes by a T cell since it specifically indicates that it is a B cell and unrelated to B cell determinant.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
December 31, 2001

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